

Statement Regarding MedDRA® Subscription Licensing Agreement

The MedDRA subscription license gives the subscriber the right to use MedDRA within the subscriber's company/environment for one year. This license must be renewed each year in order to continue using MedDRA.

Data may be freely exchanged between subscribing companies. If there is a question as to a company subscription status, the MSSO will respond to requests sent to the MSSO help desk at MSSOhelp@ngc.com. Email is the preferred communication so as to provide a documented response.

Sharing MedDRA data with a non-subscribing company is a violation of the MedDRA subscription license, since this is contrary to the clause that states a subscriber cannot "distribute the MedDRA terminology to a third party." As stated above, if there is a question as to another company's subscription status you can contact the MSSO help desk.

The MSSO is taking action in an attempt to reduce the financial burden on our subscribers. During this past year, the MSSO has made an adjustment to the subscription levels by adding a Core 0 level to reduce the cost for small companies. The MSSO is also looking at ways to increase the size of the MedDRA subscription base since by doing so, the MSSO will be able to request from the Management Board a reduction in subscription fees. A company that uses another company's license, instead of buying their own, is preventing the MedDRA subscriber base from growing.

It is not, however, the MSSO's intention to sell licenses to every individual doctor who wishes to report an adverse event. In the past year, the MSSO has entered into licensing agreements with the National Library of Medicine in the United States and the Medicines Control Agency in the United Kingdom to make MedDRA available to individuals on a read only basis. In addition, the sole purpose of the Basic MedDRA license is to provide MedDRA to non-profit and government institutions to assist in education and research.

We hope this information will help clarify any questions you might have concerning MedDRA subscription licensing agreement. If you would like additional information, please contact us at MSSOhelp@ngc.com

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